



# OHIO STATE BOARD OF PHARMACY

77 South High Street, Room 1702; Columbus, OH 43215-6126

-Equal Opportunity Employer and Service Provider-

TEL: 614/466-4143

E-MAIL: [exec@bop.state.oh.us](mailto:exec@bop.state.oh.us)

FAX: 614/752-4836

TTY/TDD: Use the Ohio Relay Service: 1-800/750-0750

URL: <http://www.pharmacy.ohio.gov>

## ORDER OF THE STATE BOARD OF PHARMACY

(Docket No. D-000530-065)

In The Matter Of:

### **GOOD SAMARITAN HOSPITAL**

c/o Susan McBeth, R.Ph.

375 Dixmyth Avenue

Cincinnati, Ohio 45220

(Terminal Distributor No. 02-0030650)

### INTRODUCTION

THE MATTER OF GOOD SAMARITAN HOSPITAL CAME FOR HEARING ON OCTOBER 4, 2000, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: SUZANNE L. NEUBER, R.Ph. (presiding); ANN D. ABELE, R.Ph.; SUZANNE R. EASTMAN, R.Ph.; ROBERT P. GIACALONE, R.Ph.; LAWRENCE J. KOST, R.Ph.; AMONTE B. LITTLEJOHN, R.Ph.; AND JAMES E. TURNER, R.Ph.

GOOD SAMARITAN HOSPITAL WAS NOT REPRESENTED BY COUNSEL, AND THE STATE OF OHIO WAS REPRESENTED BY SALLY ANN STEUK, ASSISTANT ATTORNEY GENERAL.

### SUMMARY OF EVIDENCE

#### (A) Testimony

State's Witnesses:

- (1) William F. McMillen, Ohio State Board of Pharmacy
- (2) Elaine Jones, R.Ph., Ohio State Board of Pharmacy

Respondent's Witnesses:

- (1) Steve Porowski, Responsible Pharmacist, Bethesda Hospital-North
- (2) Susan McBeth, R.Ph., Responsible Pharmacist, Good Samaritan Hospital

#### (B) Exhibits

State's Exhibits:

- (1) Exhibit 1--Copy of four-page Notice of Opportunity for Hearing letter dated May 30, 2000.
- (2) Exhibit 1A--Hearing Request Letter dated June 26, 2000.
- (3) Exhibit 1B--Copy of Hearing Schedule letter dated July 6, 2000.
- (4) Exhibit 1C--Copy of Renewal Application for DDD License, No. 02-0030650, for a terminal distributor of dangerous drugs license from January 1, 2000, to December 31, 2000, of Good Samaritan Hospital signed by Susan K. McBeth dated October 20, 1999.
- (5) Exhibit 2--Copy of four-page Settlement Agreement with the State Board of Pharmacy, Docket No. D-970121-029, in the matter of Good Samaritan Hospital effective June 16, 1997.
- (6) Exhibit 3--Copy of ten-page Dangerous Drug Distributor Inspection Report of Good Samaritan Hospital dated December 21, 1999.
- (7) Exhibit 4--Two-page copy of response to pink sheet signed by Susan McBeth, not dated.
- (8) Exhibit 5--Copy of three-page Dangerous Drug Distributor Inspection Report of Good Samaritan Hospital dated February 8, 1996.
- (9) Exhibit 6--Two-page copy of response to pink sheet, not dated.

- (10) Exhibit 7--Copy of six-page Dangerous Drug Distributor Inspection Report of Good Samaritan Hospital dated September 30, 1998; and copy of Licensure Information for the Pharmacy Department dated from 1998 through 1999.
- (11) Exhibit 8--Copy of Dangerous Drug Distributor Inspection Report of Good Samaritan Hospital dated August 27, 1997.

Respondent's Exhibits:

- (1) Exhibit A--Copy of four-page Notice of Opportunity for Hearing letter dated May 30, 2000.
- (2) Exhibit B--Copy of response to the allegations sent to Good Samaritan Hospital on May 30, 2000, not dated.
- (3) Exhibit C--Copy of letter from G. Keith Bullock dated May 28, 1999.

FINDINGS OF FACT

After having heard the testimony, observed the demeanor of the witnesses, considered the evidence, and weighed the credibility of each, the State Board of Pharmacy finds the following to be fact:

- (1) Records of the State Board of Pharmacy indicate that Susan McBeth is the Responsible Pharmacist at Good Samaritan Hospital pursuant to Sections 4729.27 and 4729.55 of the Ohio Revised Code and Rule 4729-17-02 of the Ohio Administrative Code.
- (2) Records further indicate that Good Samaritan Hospital entered into a Settlement Agreement with the State Board of Pharmacy, Docket No. D-970121-029, dated June 16, 1997. The terms of the Settlement Agreement include: a monetary penalty of six thousand dollars (\$6,000.00) and proof of compliance with Ohio and federal laws, rules, and regulations. Contrary to the terms of the Settlement Agreement, Good Samaritan Hospital has failed to show compliance with Ohio and federal laws, rules, and regulations.
- (3) Good Samaritan Hospital, an institutional pharmacy, on or about December 21, 1999, and dates immediately preceding, failed to maintain records of positive identification of the pharmacist responsible for performing all activities relating to the practice of pharmacy when entering prescription information into the recordkeeping system, to wit: Good Samaritan Hospital pharmacists use a password without a second means to meet positive identification requirements. Such conduct is in violation of Rule 4729-5-27(A) of the Ohio Administrative Code.
- (4) Good Samaritan Hospital, an institutional pharmacy, on or about December 21, 1999, and dates immediately preceding, failed to make all records relating to the practice of pharmacy readily available and promptly produced upon request for inspection by State Board of Pharmacy officers, agents, and/or inspectors during regular business hours, to wit: Good Samaritan Hospital discarded physicians' orders after thirty days from the time they were entered into the computer system and were not produced when requested. Such conduct is in violation of Rule 4729-5-27(H) of the Ohio Administrative Code.
- (5) Good Samaritan Hospital, an institutional pharmacy, on or about December 21, 1999, and dates immediately preceding, failed to store adulterated drugs in a separate and secure area apart from the storage of drugs used for dispensing and administration, to wit: State Board of Pharmacy Specialists observed expired drugs on the shelves with non-expired drugs. Such conduct is in violation of Rule 4729-9-17 of the Ohio Administrative Code.
- (6) Good Samaritan Hospital, an institutional pharmacy, on or about December 21, 1999, and dates immediately preceding, failed to have the Responsible Pharmacist ensure adherence to Rule 4729-17-02 of the Ohio Administrative Code, to wit: Good Samaritan Hospital's Responsible Pharmacist, Susan McBeth, did not properly assure adherence to policies and procedures for the safe and efficient distribution of drugs in all areas of the institution; ensure responsibility for the security and control of all drugs within the institution; maintain all records, required by state or federal law to be kept at the licensed location, of the acquisition, use, distribution, and disposition of all drugs; and implement written policies and procedures which were to be consistent with Chapter 4729-17 of the Ohio Administrative Code and other applicable federal and state laws and rules governing the legal distribution of drugs. Such conduct is in violation of Rule 4729-17-02(C) of the Ohio Administrative Code.
- (7) Good Samaritan Hospital, an institutional pharmacy, on or about December 21, 1999, and dates immediately preceding, failed to maintain records of all drug orders and records relating to the practice of pharmacy, to wit: though such orders and records may be microfilmed or retained by

any process providing an exact duplicate of the original order, Good Samaritan Hospital did not maintain any such records. In addition, there was no alternate system of recordkeeping utilized, allowing such records to be stored on any storage medium that meets industry standards for quality having stability, for a period of at least three years. Records on an automated data processing system, or subsequent storage of such records, were not readily retrievable (via CRT display or hard-copy printout) within seventy-two hours. Such conduct is in violation of Rule 4729-17-04(B) of the Ohio Administrative Code.

#### CONCLUSION OF LAW

- (1) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (3) through (7) of the Findings of Fact constitute violating rules of the Board as provided in Division (A)(2) of Section 4729.57 of the Ohio Revised Code.

#### ACTION OF THE BOARD

Pursuant to Section 4729.57 of the Ohio Revised Code, and on the basis of the Findings of Fact and Conclusion of Law set forth above, the State Board of Pharmacy takes the following actions in the matter of Good Samaritan Hospital:

- (A) The State Board of Pharmacy hereby imposes a monetary penalty of five thousand dollars.
- (B) Further, the Board will suspend two thousand five hundred dollars of the five thousand-dollar monetary penalty provided that Good Samaritan Hospital comply with the terms of this Order. The monetary penalty of two thousand five hundred dollars (\$2,500.00) is due and owing within thirty days of the issuance of this Order. The monetary penalty should be made payable to the "Treasurer, State of Ohio" and mailed with the enclosed form to the State Board of Pharmacy, 77 South High Street, Room 1702, Columbus, Ohio 43215-6126. Other terms of this Order are as follows:
  - (1) Good Samaritan Hospital must correct the violations noted in the Findings of Fact stated herein within ninety days of the effective date of this Order and notify the State Board of Pharmacy Compliance Specialist in its area that the corrections have been made. The specialist will conduct an inspection within the ninety-day period. The inspection must show compliance with Ohio and federal laws, rules and regulations.
  - (2) Good Samaritan Hospital will be subject to inspection annually for three years.
  - (3) Good Samaritan Hospital must notify the Board of any proposed changes to its policies and procedures before implementation.

THIS ORDER WAS APPROVED BY A VOTE OF THE STATE BOARD OF PHARMACY.

MOTION CARRIED.

SO ORDERED.



# OHIO STATE BOARD OF PHARMACY

77 South High Street, Room 1702; Columbus, OH 43215-6126

-Equal Opportunity Employer and Service Provider-

TEL: 614/466-4143

E-MAIL: [exec@bop.state.oh.us](mailto:exec@bop.state.oh.us)

FAX: 614/752-4836

TTY/TDD: Use the Ohio Relay Service: 1-800/750-0750

URL: <http://www.pharmacy.ohio.gov>

## SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY

(Docket No. D-970121-029)

In The Matter Of:

### **GOOD SAMARITAN HOSPITAL**

c/o Susan K. McBeth, R.Ph.

3217 Clifton Avenue

Cincinnati, Ohio 45220

(Terminal Distributor No. 02-0030650)

This Settlement Agreement is entered into by and between Good Samaritan Hospital and the Ohio State Board of Pharmacy, a state agency charged with enforcing the Pharmacy Practice Act and Dangerous Drug Distribution Act, Chapter 4729. of the Ohio Revised Code.

Good Samaritan Hospital enters into this Agreement being fully informed of its rights afforded under Chapter 119. of the Ohio Revised Code, including the right to representation by counsel and the right to a formal adjudication hearing on the issues contained herein.

Good Samaritan Hospital is knowingly and voluntarily acknowledging that, in order to settle the charges that have been filed by the Board against Good Samaritan Hospital, and in order to obviate the need to conduct an administrative hearing to consider the disciplinary sanctions against Good Samaritan Hospital's license, this Agreement is entered into on the basis of the following stipulations, admissions, and understandings:

- (A) The Ohio State Board of Pharmacy is empowered by Section 4729.57 of the Ohio Revised Code to suspend, revoke, refuse to renew, or impose a monetary penalty on any terminal distributor of dangerous drugs for violation of any of the enumerated grounds.
- (B) On or about January 21, 1997, Good Samaritan Hospital was notified of the allegations or charges against it, its right to a hearing, its rights in such hearing, and its right to submit contentions in writing. Further, in accordance with Chapter 119. of the Ohio Revised Code, a hearing was requested and scheduled for June 18, 1997.
- (C) Good Samaritan Hospital stipulates to the allegations stated in the Notice of Opportunity letter dated January 21, 1997, and the Board herein adjudicates the same:
  - (1) Records of the Board of Pharmacy indicate that Susan K. McBeth is the Responsible Pharmacist at Good Samaritan Hospital, a terminal distributor of dangerous drugs licensed with the Board, pursuant to Sections 4729.27 and 4729.55 of the Ohio Revised Code and Rule 4729-17-02 of the Ohio Administrative Code.
  - (2) Good Samaritan Hospital, an institutional pharmacy, did, on or about February 5, 1996, and dates immediately preceding, fail to have a pharmacist ensure adherence to Rule 4729-17-02 of the Ohio Administrative Code, to wit: the Responsible Pharmacist did not properly: a) assure adherence to policies and procedures for the safe and efficient distribution of drugs in all areas of the institution; b) ensure responsibility for the security and control of all drugs within the institution; c) maintain all records, required by state or federal law to be kept at the licensed location, of the acquisition, use, distribution, and disposition of all drugs; d) implement written policies and procedures which were to be consistent with Chapter 4729-17 of the Ohio Administrative Code and other applicable federal and state laws and rules governing the legal distribution of drugs. Such conduct is in violation of Rule 4729-17-02 of the Ohio Administrative Code.

- (3) Good Samaritan Hospital, an institutional pharmacy, did, on or about February 5, 1996, and dates immediately preceding, fail to maintain records of all drug orders and dispensing records for drugs for patients. Though such drug orders and dispensing records may be microfilmed or retained by any process providing an exact duplicate of the original order, the pharmacy did not maintain any such records. In addition, there was no alternate recordkeeping system utilized allowing such records to be stored on electronic, magnetic, light, laser, or optic media meeting industry standards for quality and stability for a period of at least three years. Records on an automated data processing system, or subsequent storage of such records, were not readily retrievable (via CRT display or hard-copy printout) within seventy-two hours. Records of drugs dispensed did not include the name, strength, and quantity of drugs dispensed; the date of dispensing; the name of the inpatient to whom, or for whose use, the drug was dispensed; or positive identification of the dispensing pharmacist. Such conduct is in violation of Rule 4729-17-04(B) of the Ohio Administrative Code and Section 3719.07 of the Ohio Revised Code.
- (4) Good Samaritan Hospital, an institutional pharmacy, did, on or about February 5, 1996, and dates immediately preceding, cease to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in Section 4729.55 of the Ohio Revised Code, to wit: adequate safeguards were not assured to prevent the sale or other distribution of dangerous drugs by persons other than a pharmacist, dentist, optometrist, physician, or veterinarian in that recordkeeping, security, and control over the dangerous drugs, and/or hospital pharmacy procedures were inadequate and/or non-existent to such a degree as to permit thefts and perpetrators of thefts of controlled substances to remain undetected. Records of drugs dispensed and/or returned to the pharmacy did not exist beyond three days after the activity of dispensing. Dispensing records consisted of copies of Medication Administration Records sent to the pharmacy, created by nursing on the floor at the time of administration, but did not actually record the number of doses dispensed by or returned to the pharmacy.

Wherefore, in consideration of the foregoing and mutual promises hereinafter set forth, and in lieu of any formal proceedings at this time, Good Samaritan Hospital knowingly and voluntarily agrees with the State Board of Pharmacy to the following:

- (A) Good Samaritan Hospital agrees to the imposition of a monetary penalty of six thousand dollars (\$6,000.00) due and owing within thirty days of the effective date of this Agreement. The monetary penalty should be made payable to the "Treasurer, State of Ohio" and mailed with the enclosed form to the State Board of Pharmacy, 77 S. High Street, 17th Floor, Columbus, Ohio 43266-0320.
- (B) The Board has directed Board staff to conduct an inspection within ninety days from the effective date of this Agreement. The inspection must show compliance with Ohio and federal laws, rules, and regulations. Further inspections will be held at least annually for three years thereafter.

If, in the judgment of the Board, Good Samaritan Hospital appears to have violated or breached any terms or conditions of this Agreement, the Ohio State Board of Pharmacy reserves the right to, at any time, institute formal disciplinary proceedings for any and all possible violations or breaches, including but not limited to, alleged violation of the laws of Ohio occurring before the effective date of this Agreement.

Good Samaritan Hospital acknowledges that it has had an opportunity to ask questions concerning the terms of this agreement and that all questions asked have been answered in a satisfactory manner. Any action initiated by the Board based on alleged violation of this Agreement shall comply with the Administrative Procedure Act, Chapter 119. of the Ohio Revised Code.

Good Samaritan Hospital and its employees and agents waive any and all claims or causes of action they may claim against the State of Ohio or the Board, and members, officers, employees, and/or agents of either, arising out of matters which are the subject of this Agreement.

In the event the Board, in its discretion, does not adopt this Agreement as its Adjudication, this settlement offer is withdrawn and shall be of no evidentiary value and shall not be relied upon or introduced in any disciplinary action or appeal by either party. Good Samaritan Hospital agrees that should the Board reject this Agreement and if this case proceeds to hearing, it will assert no claim that the Board was prejudiced by its review and discussion of this Agreement or of any information relating thereto.

This Settlement Agreement shall be considered a public record, as that term is used in Section 149.43 of the Ohio Revised Code, and shall become effective upon the date of the Board President's signature below.

/s/ Susan K. McBeth  
Susan K. McBeth on behalf of Good Samaritan Hospital  
Responsible Pharmacist

/d/ 5/27/97  
Date of Signature

/s/ Kris M. Dawley  
Kris M. Dawley, Attorney for Respondent

\_\_\_\_\_  
Date of Signature

/s/ Suzanne L. Neuber  
Suzanne L. Neuber, President, Ohio State Board of Pharmacy

/d/ 6/16/97  
Date of Signature

/s/ Mary L. Hollern  
Mary L. Hollern, Ohio Assistant Attorney General

/d/ 6/16/97  
Date of Signature